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EXAMINER

WANG, CHANG YU

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Continuation of 11. does NOT place the application in condition for allowance because:
Applicant's arguments have been fully considered but they are insufficient to overcome the rejection under 112-1st, lack of scope of enablement, the rejection under 102(b), the rejection under 102(b)/103(a) and the rejection under 103(a). The rejections are maintained for the reasons made of record in the office mailed 9/18/08.

Claims 2-5, 8, 9, 11 and 14-16 stand rejected under 35 U.S.C. 102 (b) as being anticipated by Walker et al (1994), Pirttila et al. (1994), WO0162801 or Naslund et al..

Claims 2, 5, 8, and 14-16 stand rejected under 35 U.S.C. 102 (b) as being anticipated by Solomon et al. (1996). Claims 2, 5, 8, and 14-16 stand rejected under 35 U.S.C. 102 (a) as being anticipated by Huse et al. (2002).

Claims 2-5, 8, 9, 11 and 14-16 stand rejected under 35 U.S.C. 103(a) for being unpatentable over Huse et al. (2002) in view of Walker et al (1994) and WO0162801.

Claims 2, 6, 7, 15 and 16 stand rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent No. 6984720.

Claims 2-11 and 14-16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Huse et al. (2002) in view of Walker et al (1994) and WO0162801 as applied to claims 2-5, 8, 9, 11 and 14-16 above, and further in view of US Patent No. 6984720.

Applicant argues that none of the cited antibodies 10D5 (Walker,1994), 4G8 (Pirttila,1994), BNT77 (Huse et al.), 266 (WO0162801), 6E10 (Naslund,1994), AMY-33 and 6F/3D (Solomon) teaches the claimed antibodies that recognize Abeta11-x peptides without cross-reacting with full length Abeta1-40/42 peptide. In response, as previously made of record, the product claimed by Applicant has the same function, property or characteristics as that of the prior art products. If the epitope to which Applicant's antibody binds is present in A β 11-x, so that Applicant's antibody binds to A β 11-x, it is also present in A β 1-16, 1-38, 1-24, 1-17, 17-24,

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11-28, 8-17 and 13-28 as disclosed by the cited references. Applicant fails to provide side-by-side comparisons to demonstrate that the claimed antibody is different from those antibodies disclosed by Walker et al., Pirtila, WO0162801, Naslund and Solomon. **Note that**

"Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). 'When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.' In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433." See MPEP § 2112.01 [R-3].

In addition, as previously made of record, the claimed hybridoma cells are also named 5C4 as described on p.22 of the instant specification. The 5C4 monoclonal antibody disclosed by the '720 patent has the same name as the claimed hybridoma cells as recited in claims 6 and 7 based on the instant specification (see p.22 of the instant specification) and can also block amyloid accumulation in Alzheimer's patients (see col.9, lines 47-62.). Applicant fails to demonstrate that the 5C4 monoclonal antibody disclosed by the '720 patent is structurally and functionally different from the claimed antibody hybridoma cells 5C4 as described in the specification. Since the 5C4 monoclonal antibody of the '720 patent can block amyloid accumulation in AD patients, it indicates that the 5C4 monoclonal antibody of the '720 patent has the same property and function as the claimed antibody, which is also capable of binding to A β 11-x. Thus, the binding of the '720 patent's 5C4 monoclonal antibody to A β 11-x would be an inherent feature of the antibody.

Claims 14 and 16 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detection of Abeta11-40 in the CSF and brain section of Alzheimer's disease by using antibodies raised against Abeta peptides consisting of 6-8 amino acids of Abeta₁₁ (6AA) or Abeta₈ (8AA) (SEQ ID NOs: 1-4), does not reasonably provide

enablement for using the antibodies that specifically bind to Abeta11-x peptides to diagnose all amyloid-related diseases as broadly claimed.

Claim 16 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite because of the recitation of “support”.

Applicant argues that a skilled artisan can diagnose all of the recited diseases in claims 14 and 16 because amyloid deposits are characterized in the brains of patients with the recited diseases and Abeta11-40 is a major species in the brains of patients with Alzheimer’s disease and Down’s syndrome as supported at paragraphs [0004]-[0006]. In response, the specification only teaches detection of Abeta11-40 in AD but fails to teach whether Abeta11-40 can be detected in other diseases as recited in the claims. In addition, the specification fails to demonstrate that the amyloid deposits in AD are the same species as in other diseases and thus can be used to diagnose other diseases. Further, there are different species of Abeta peptides in amyloid deposits. The specification fails to establish a correlation between Abeta11-40 and other species in AD or in other diseases. Thus, it is unpredictable whether the claimed antibodies can be used to diagnose other diseases recited in claims 14 and 16.

In addition, Applicant argues that the recitation of “solid support” is known in the art. As previously made of record, the specification fails to define/describe what is encompassed in the definition of “solid support”. The metes and bounds of what are encompassed within the definition of such solid support cannot be determined; thus the claim is indefinite.

/CYW/
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1/29/09

/Jeffrey Stucker/
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